National Cancer Medicines Advisory Group (NCMAG) Programme

Council | Terms of Reference (ToR)

January 2022

Document Version: 4.0
# Document Control Sheet

## Key Information

<table>
<thead>
<tr>
<th>Title:</th>
<th>NCMAG Council TOR</th>
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<tr>
<td>Version Number:</td>
<td>Version 1.0</td>
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<tr>
<td>Document Type</td>
<td>Terms of Reference</td>
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<tr>
<td>Document status:</td>
<td>Approved</td>
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<tr>
<td>Date of approval:</td>
<td>19/03/2022</td>
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<tr>
<td>Author:</td>
<td>NCMAG Programme Team</td>
</tr>
<tr>
<td>Owner:</td>
<td>NCMAG Programme Team</td>
</tr>
<tr>
<td>Approver:</td>
<td>Dr Sally Clive, NCMAG Chair</td>
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## Document updates

<table>
<thead>
<tr>
<th>Version No.</th>
<th>Summary of changes</th>
<th>Approval date</th>
<th>Approved by</th>
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<tr>
<td>v2.0</td>
<td>Inclusion of additional processes and steps for Council members, Proposer and Patient Group Partners.</td>
<td>08/07/22</td>
<td>Dr Sally Clive, NCMAG Chair</td>
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<td>v3.0</td>
<td>Updated section 5.11; 5.12.2 and Appendix 2</td>
<td>11/08/2022</td>
<td>Dr Sally Clive, NCMAG Chair</td>
</tr>
<tr>
<td>V4.0</td>
<td>Updated membership Appendix 2 &amp; 4, added section 4.1.4; 4.3</td>
<td>02/03/2023</td>
<td>Dr Sally Clive, NCMAG Chair</td>
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</table>
1. Purpose

The purpose of the National Cancer Medicines Advisory Group (NCMAG) Council (hereafter referred to as 'The Council') is to support NCMAG in providing advice on cancer medicines, through members contributing their health and care expertise and experience.

The Council is responsible for making recommendations to NHSScotland on off-label uses of licensed medicines: branded, generic or biosimilar and on-label uses of licensed generic medicines (known as off-patent use), all of which are out with the remit of the Scottish Medicines Consortium (SMC). In more detail, the remit of NCMAG includes:

- Off-label uses of cancer medicines, based on emergent evidence, or may include established off-label uses where there is concern regarding inconsistency or inequity of access across Scotland. Broadly, this may include uses:
  - for an illness not specified within the marketing authorisation
  - for administration by a different route
  - for administration of a different dose and/or frequency
  - for a different patient population
- On-label (licensed) uses which are not recommended by SMC, however the patent has expired since SMC advice was published, with the medicine currently available at lower cost and where current cost-effectiveness has not been reviewed.

The Council makes recommendations based on the evidence presented to the Council.

The Healthcare Improvement Scotland (HIS) Executive Team greatly values the contribution of members who serve on the Council. Their service and commitment, along with the expertise and knowledge they bring, contributes directly to improving outcomes for patients in NHSScotland.

2. Governance

- The Council is responsible for agreeing recommendations.
- The Council Chair is accountable to the HIS Board on behalf of the Council for all recommendations made by the Council.
- The Council is informed by the NCMAG Executive Team on the strategic direction for the work of NCMAG.
- The Council engages with the NCMAG Executive Team in considering methodologies and ways of working to ensure the recommendations from NCMAG are robust and reliable and based on best practice.
- The Council operates within HIS policies and procedures.
- HIS reserves the right to delay or refuse publication of any outputs if there are concerns about the quality or validity of the findings.
- In circumstances where urgent decisions are required and it is impractical to convene an extraordinary meeting of the Council, the NCMAG Executive Group will ensure that the Council is informed.
- Legal indemnity: all recommendations from the Council are covered by the Clinical Negligence and Others Indemnity Scheme (CNORIS).
2.1 Reporting

The Council provides regular updates to the NCMAG Executive Team, through the Chair. The overall NCMAG programme reporting structure is illustrated in the diagram in Appendix 6. Significant risks or issues are escalated to the HIS Executive Team by the HIS Medical Director.

3. Responsibilities

3.1 Collective Responsibilities of the Council

- Review proposal information presented to the Council, including associated comments and, after discussion, agree wording of advice. Advice is based on the range of evidence presented to the Council, submitted Patient Group Partner statements, other cogent factors of relevance to NHSScotland as well as members’ knowledge and experience of the Scottish context.
- Provide comment on the strategic direction for NCMAG’s work.
- Provide comment on new methodologies and ways of working to ensure the advice from the group is robust and reliable and based on best practice.
- Inform the programme team of new evidence that is likely to materially change previously published ‘advice’ on a topic that is still of current interest within NHS Scotland.
- Provide a forum for sharing information about NCMAG advice development, dissemination, implementation and related activities.
- Maintain an awareness of developments in the field of HTA taking place nationally and internationally and consider their applicability within Scotland.
- Act collectively in accepting and agreeing the business of meetings.

3.2 Responsibilities of individual members of the Council

- Make a full commitment to support the function and work of NCMAG.
- Attend all meetings of the Council or arrange for a deputy to attend. Highlight areas of concern to the Chair of the Council.
- Read all meeting papers in advance of the meetings.
- Agree to lead discussion on specific topics and pieces of work, as requested by the Chair of the Council.
- Participate in and contribute to working groups/subgroups, where requested by the Chair of the Council.
- Use professional expertise and networks to highlight cancer medicines of relevance for consideration by NCMAG.
- Raise awareness of NCMAG and its role and remit, facilitating engagement with their constituent geographical and professional networks and clinical communities.
- Adhere to the HIS organisational values and behaviours: care and compassion; dignity and respect; quality and teamwork; and openness, honesty and responsibility.
- Make a full declaration of interests on appointment, and annually thereafter, in accordance with the HIS Evidence Directorate policy on declaration of interests. If a
member is uncertain as to whether or not an interest should be declared, they must seek guidance from the Chair. All Council members are required to declare relevant interests at meetings, whether or not those interests have previously been declared to NCMAG. Declarations of interest may be published online.

**PLEASE NOTE** | Any statements relating to the members of the Council throughout the ToR apply equally to deputies.

4. Membership

- Members are appointed on the basis of their experience and expertise and as representatives of their professional networks, including lay representatives. For representatives of an organisation, we would anticipate consulting with your network where appropriate but are not expecting full consultation within the organisation on all papers.
- The membership of the Council is made public via the NCMAG webpage.
- Members of the Council are appointed by HIS, in consultation with the NCMAG Executive Team, for a period of 3 years. This may be renewed on the recommendation of the NCMAG Executive Team and with the agreement of the member, and his/her nominating body, for a further term of 3 years or longer in exceptional circumstances.
- Additional representatives may be appointed as members of the Council at the discretion of the NCMAG Executive Team.

4.1 Members

Membership of the Council comprises of multidisciplinary attendance and representation of the following groups and organisations:

4.1.1 NCMAG Team attendance (Appendix 1) consists of:

- HIS National Clinical Lead – Cancer Medicines
- NCMAG Lead Pharmacist
- NCMAG Senior Project Officer
- NCMAG Project Officer
- NCMAG Health Service Researchers (2)
- NCMAG Pharmaceutical Analyst
- NCMAG Health Economist

4.1.2 Full NCMAG Council membership (Appendix 2) consists of:

- NCMAG Chair
- 2 Area Drug and Therapeutics Committee (ADTC) representatives (for example an ADTC chair and a formulary pharmacist)
- 1 Directors of Finance (for example Director of Finance or Senior Manager)
- 1 NHS Scotland Directors of Pharmacy Group
- 1 National Acute Pharmacy Group Scotland (NAPS)
- 1 North Cancer Alliance (NCA) pharmacy
• 1 NCA medical
• 1 NHS Board Senior Cancer Service Manager
• 1 or 2 Public Partners, Healthcare Improvement Scotland
• 1 South East Scotland Cancer Network (SCAN) medical
• 1 SCAN pharmacy
• 1 West of Scotland Cancer Network (WoSCAN) medical
• 1 WoSCAN pharmacy

4.1.3 Special NHS Board stakeholders (Appendix 3) in attendance include:
• 1 Scottish Intercollegiate Guideline Network (SIGN) representative (for example Programme Lead)
• 1 SMC (Principal Health Economist)
• 1 SMC (Principal Pharmaceutical Analyst)
• 1 NHS National Services Scotland, National Procurement
• 1 Scottish Cancer Network (SCN) representative
• 1 HIS ADTC Collaborative representative

4.1.4 Special NHS Board associate stakeholders (Appendix 3) in attendance include:
• 1 Scottish Strategic Network for Genomic Medicine (SSNGM)

4.1.5 Observer (Appendix 5) status:
• 1 Scottish Government Health Department

4.2 In attendance

Those ‘in attendance’ may contribute to the discussion during the meeting, but are not permitted to participate in the decision-making, which is the responsibility of Council members. Those ‘in attendance’ include:

• NCMAG Programme Team
• Special NHS Board stakeholders (Appendix 3)
• Special NHS Board associate stakeholders (Appendix 4)
• Observer (Appendix 5)
• Patient Group Partners representatives
• Organisations not already represented on NCMAG Council with a relevant interest in the work of NCMAG, who may be invited to attend and participate in the meetings with the agreement of the Chair.
• Cancer type-specific experts/proposers, who will routinely be invited to attend Council meetings to provide evidence for Council members’ consideration.

Other NHS staff, who may be invited to attend meetings to address specific items of business or may wish to attend as observers.
4.3 **Associate Council Member/s**

4.3.1 **Scottish Strategic Network for Genomic Medicine (SSNGM)**

SSNGM representative will:

- work with the NCMAG membership and programme team, providing a link with the SSNGM, when there are specific molecular or genomics issues to be considered
- review proposals submitted to NCMAG and the draft advice document and contribute to the discussion,
- attend NCMAG Council meetings as necessary to provide a genomic medicine perspective, where relevant to specific proposals (these take place every 3 months on Thursdays for up to 3 hours)
- engage with NCMAG horizon scanning activities where there are specific genomic or molecular considerations for identified medicines

4.4 **Patient Group Partners**

One nominated representative from each Patient Group that submitted a statement on the proposed treatment will be invited to attend the NCMAG Council meeting to clarify any points raised in relation to patient and carer issues. At the discretion of the Chair, the patient group representative(s) may respond to any specific questions from Council members about their statement submission to NCMAG.

5. **Meetings**

5.1 **Frequency of meetings**

- The Council will meet every two or three months and meetings may last up to three hours. Details of meeting format and / or location is provided in advance of the meeting.
- An annual schedule of meetings for the following calendar year is produced.
- The Chair, or Vice Chair in their absence, may convene extraordinary meetings of the Council, if required.
- Optional development sessions may be offered for members as agreed by NCMAG Executive Team.

5.2 **Agenda and papers**

- The NCMAG Executive Team determines which items appear on the Council meeting agenda.
- Members of the Council may submit items for consideration. Any member wishing to have an item considered for an agenda should notify the NCMAG Team at as early a date as possible.
- NCMAG members will receive the agenda and papers (Proposal submission/s, draft NCMAG Advice Document/s, Patient Group Partners Statement submission/s) at least
five working days in advance of the NCMAG Council meeting. The order of business is determined by the Chair.

- The agenda only is shared with Patient Group Partner/s and Proposer/s at least five working days in advance of NCMAG Council meeting.
- Tabled papers may be accepted with the express agreement of the Chair and only in exceptional circumstances.
- No other business is discussed at the meeting, unless permitted by the Chair.

### 5.3 Conduct of meetings

- Meetings are conducted by the Chair, or the Vice Chair in their absence. The Chair must ensure that all members of the Council feel able to contribute fully to the advice formulation processes. The Chair leads and directs meetings, encouraging all members to make a full contribution to discussions and ensuring that all appropriate matters are addressed in a timely manner.
- NCMAG Council members, where possible, should use accessible language (plain English) at the NCMAG Council meetings to support the understanding of Patient Group Partners and Public Partner Council members.
- The text highlighted within the draft NCMAG Advice Documents tabled at the Council meetings will be to indicate different types of confidential information, either academic in confidence or commercial in confidence. To retain confidentiality in the presence of non-council members the highlighted information should not be stated verbally at the meeting. Indirect reference (for example, the text highlighted on page 9) and discussion not revealing this information is acceptable.

### 5.4 Timekeeping

The agenda is timed with the discretion of the chair to be flexible to ensure appropriate discussion and decision-making. Rarely, un-concluded items are carried forward to the next meeting or concluded in writing.

### 5.5 Attendance and Format

- Members except associate members (refer to section 4.3.1) are expected to attend all meetings. The substitution of a deputy is acceptable on the understanding that the deputy will be able to contribute to the discussion and provide a report on the meeting to the substantive member. Members submitting apologies for meetings, and who are unable to send a deputy, are expected to notify the NCMAG Team in advance.
- All reasonable facilities are provided for members to ensure they can participate fully and equitably in the business of the Council.
- If a member does not attend or send a deputy for three consecutive meetings, the Chair will consider whether they should continue as a member.

### 5.6 Interpretation
During the meeting, the Chair of the Council has overall responsibility for the interpretation of the Terms of Reference. Statements made by members during the meeting should be relevant to the matter under discussion.

5.7 Collective Decision-Making

- Only full members will be involved in the final decision-making process. Those members are clinicians, NHS managers and public partners. Those in attendance at the meetings, including NCMAG Programme Team, other HIS staff, national board staff and invited clinical experts may contribute to the discussion but are not eligible to express a view in the final decision-making process. All members act collectively in accepting and agreeing the business of meetings and ensure the discussions and conclusions remain confidential until the publication of the minutes and outputs. Decisions are taken by reaching consensus among the majority of full members present through discussion. A full member shall have the right for their dissent to be recorded.

- The proposer/s, anyone with relevant conflicts of interest, those ‘in attendance’ and Patient Group Partner representative/s are invited to leave the meeting immediately prior to the point of decision-making.

5.8 Declaration of interests

All Council members are required to declare relevant interests at meetings, whether or not those interests have previously been declared to NCMAG. If an issue arises for discussion and a member is concerned about a matter which could be regarded as affecting their impartiality and this matter has not already been declared, they must raise this with the Chair in advance of the meeting if possible. The Chair must also ensure that at the beginning of each meeting members are asked to declare any additional recently acquired interests, and implement the HIS Evidence policy on handling declarations of interest.

5.9 Confidentiality

NCMAG requests that confidentiality is observed in respect of all information shared in relation to NCMAG business and that steps are taken to ensure it is not breached.

Patient Group Partner (PGP) representatives are required to complete and sign:

- NCMAG Confidentiality Statement to attend NCMAG Council meeting
- NCMAG PGP Early Release Embargoed Advice Confidentiality Agreement Form

5.10 Quorum

Council meetings are considered quorate with an attendance of 50% plus one member, including representation of at least two of the three regional cancer networks with at least one medical and one pharmacy representative. At the Chair’s discretion, meetings which are not quorate may continue if those members who are not present are consulted after the meeting and agree with the decisions reached.
5.11 Record of meeting and attendance

A record of attendance at the Council meetings and a brief meeting note will be maintained by the NCMAG Programme Team and kept internally for records. Meeting notes can be provided upon request.

5.12 NCMAG Advice Document

5.12.1 What is the Advice Document?

The advice document details the NCMAG Council decision and the reason(s) for supporting or not supporting the use of a medicine.

Once a decision has been made on the use of a medicine, the document informs NHS Boards to support decision making for local use and local formulary inclusion.

5.12.2 Timetable and Circulation

<table>
<thead>
<tr>
<th>One working week after NCMAG Council meeting</th>
<th>NCMAG Programme Team (Appendix 1)</th>
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<tr>
<td>the embargoed NCMAG Advice Document will be</td>
<td>NCMAG Council representation (Appendix 2,3 and 4)</td>
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<td>circulated to the following contacts:</td>
<td>Regional Cancer Network Leads</td>
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<tr>
<td></td>
<td>Scottish Government Health Department, Medicines and Policy Teams contacts</td>
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<td></td>
<td>Scottish Medicines Consortium (SMC) contacts</td>
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<td></td>
<td>SIGN contacts</td>
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<td></td>
<td>Formulary Pharmacists</td>
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<td>ADTC Chairs and Professional Secretaries</td>
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<td>Chief Executives</td>
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<td>Medical Directors</td>
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<td>Directors of Pharmacy</td>
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<td>Directors of Finance</td>
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<td></td>
<td>Scottish Cancer Network Lead Clinician and Pharmacist</td>
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| Four working weeks after the NCMAG Council meeting | embargoed NCMAG Advice Document will be circulated to Patient Group Partner representatives. (Subject to receipt of confidentiality agreement on embargoed NCMAG Advice Document) |

| Five working weeks after the NCMAG Council meeting | the final NCMAG Advice Document will be published on the NCMAG webpage. |
**Appendix 1 | Healthcare Improvement Scotland | NCMAG Programme Team | In attendance**

<table>
<thead>
<tr>
<th>Name</th>
<th>Surname</th>
<th>Job Title</th>
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<tbody>
<tr>
<td>Pamela</td>
<td>Andrews</td>
<td>Health Service Researcher, NCMAG</td>
</tr>
<tr>
<td>Hana</td>
<td>Barvik</td>
<td>Senior Project Officer, NCMAG</td>
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<tr>
<td>Louise</td>
<td>Craig</td>
<td>Health Service Researcher, NCMAG</td>
</tr>
<tr>
<td>Heather</td>
<td>Dalrymple</td>
<td>National Clinical Lead, Cancer Medicines</td>
</tr>
<tr>
<td>Louis</td>
<td>Doherty</td>
<td>Pharmaceutical Analyst, NCMAG</td>
</tr>
<tr>
<td>James</td>
<td>Drinkell</td>
<td>Health Economist, NCMAG</td>
</tr>
<tr>
<td>Rickie</td>
<td>O'Connell</td>
<td>Lead Pharmacist, NCMAG</td>
</tr>
<tr>
<td>Kate</td>
<td>Russell</td>
<td>Project Officer, NCMAG</td>
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**Appendix 2 | NCMAG Council | Full membership**

<table>
<thead>
<tr>
<th>Stakeholder representation</th>
<th>NCMAG Role</th>
<th>Name</th>
<th>Surname</th>
<th>Job Title</th>
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<tbody>
<tr>
<td>Area Drug and Therapeutics Committee (ADTC)</td>
<td>ADTC representative</td>
<td>Dianne</td>
<td>Murray</td>
<td>Formulary Pharmacist</td>
</tr>
<tr>
<td>Area Drug and Therapeutics Committees (ADTC)</td>
<td>ADTC representative</td>
<td>Ewan</td>
<td>Bell</td>
<td>National Clinical Lead – ADTC Collaborative, Healthcare Improvement Scotland</td>
</tr>
<tr>
<td>Healthcare Improvement Scotland</td>
<td>HIS Public Partner</td>
<td>David A</td>
<td>Dunkley</td>
<td>HIS Public Partner (Note: HIS Public Partner term ends in March 2024)</td>
</tr>
<tr>
<td>Healthcare Improvement Scotland</td>
<td>HIS Public Partner</td>
<td>Margaret</td>
<td>Wilson</td>
<td>HIS Public Partner (Note: HIS Public Partner term ends in March 2026)</td>
</tr>
<tr>
<td>NCMAG Programme</td>
<td>Chair</td>
<td>Sally</td>
<td>Clive</td>
<td>Consultant in Medical Oncology, NHS Lothian,</td>
</tr>
<tr>
<td>Stakeholder representation</td>
<td>NCMAG Role</td>
<td>Name</td>
<td>Surname</td>
<td>Job Title</td>
</tr>
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</tr>
<tr>
<td>NHS Board Senior Cancer Service Manager</td>
<td>NHS Board Senior Cancer Service Manager</td>
<td>Tracy</td>
<td>Baillie</td>
<td>Assistant General Manager - Cancer, Haematology, Head and Neck Services, NHS Ayrshire &amp; Arran</td>
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<td>NHS Directors of Finance Group</td>
<td>Director of Finance representative</td>
<td>Michael</td>
<td>McLuskey</td>
<td>Deputy Director of Finance, NHS Lanarkshire</td>
</tr>
<tr>
<td>NHS Scotland Director of Pharmacy Group</td>
<td>Director of Pharmacy representative</td>
<td>Ian</td>
<td>Rudd</td>
<td>Director of Pharmacy, NHS Highland</td>
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<tr>
<td>National Acute Pharmacy Services (NAPS) Group</td>
<td>NAPS group representative</td>
<td>Melinda</td>
<td>Cuthbert</td>
<td>Associate Director of Pharmacy, NHS Lothian</td>
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<td>North Cancer Alliance (NCA), Pharmacy</td>
<td>Senior Pharmacist representative</td>
<td>Judith</td>
<td>Jordan</td>
<td>Regional Lead Pharmacist, North Cancer Alliance</td>
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<tr>
<td>North Cancer Alliance (NCA), Medical</td>
<td>Senior Cancer Clinician representative</td>
<td>Charlotte</td>
<td>Robertson</td>
<td>Consultant Haematologist, NHS Grampian</td>
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<tr>
<td>South East Scotland Cancer Network (SCAN), Pharmacy</td>
<td>Lead Cancer Care Pharmacist</td>
<td>Jen</td>
<td>Morrison</td>
<td>Lead Cancer Care Pharmacist, NHS Lothian</td>
</tr>
<tr>
<td>South East Scotland Cancer Network (SCAN), Medical</td>
<td>Senior Cancer Clinician representative</td>
<td>David A</td>
<td>Cameron</td>
<td>Consultant in Medical Oncology, NHS Lothian</td>
</tr>
<tr>
<td>West of Scotland Cancer Area Network (WoSCAN), Medical</td>
<td>Senior Cancer Clinician representative</td>
<td>Rob</td>
<td>Jones</td>
<td>Consultant in Medical Oncology, NHS Greater Glasgow and Clyde</td>
</tr>
<tr>
<td>West of Scotland Cancer Area Network (WoSCAN), Pharmacy</td>
<td>Senior Pharmacist</td>
<td>Joanne</td>
<td>Robinson</td>
<td>Senior Cancer Pharmacist, NHS Forth Valley</td>
</tr>
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</table>

**Appendix 3 | NCMAG Council | Special NHS Board stakeholders | In attendance**
<table>
<thead>
<tr>
<th>Stakeholder representation</th>
<th>NCMAG Role</th>
<th>Name</th>
<th>Surname</th>
<th>Job Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scottish Strategic Network for Genomic Medicine (SSNGM)</td>
<td>SSNGM clinical representative</td>
<td>Patricia</td>
<td>Roxburgh</td>
<td>Lead Clinician</td>
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**Appendix 5 | NCMAG Council | Observer**

<table>
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<tr>
<th>Stakeholder representation</th>
<th>NCMAG Role</th>
<th>Name</th>
<th>Surname</th>
<th>Job Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scottish Government Health Department, Medicines Policy and Cancer Policy representative</td>
<td>SGHD Observer</td>
<td>Rachel</td>
<td>Reel</td>
<td>Senior Policy Manager, Cancer Policy</td>
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